Message Text

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70
ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 ISO-00 OES-05 /034 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: MACODDING
ARA/EX:KDACKERMAN(INFO)
---------- 097705
P 022212Z MAR 76
FM SECSTATE WASHDC
TO AMEMBASSY SANTIAGO PRIORITY
AMEMBASSY SAN JOSE PRIORITY
AMEMBASSY SANTO DOMINGO PRIORITY
AMEMBASSY SAN SALVADOR PRIORITY
AMEMBASSY GUATEMALA PRIORITY
AMEMBASSY TEGUCIGALPA PRIORITY
AMEMBASSY MANAGUA PRIORITY
AMEMBASSY LIMA PRIORITY
AMEMBASSY MONTEVIDEO PRIORITY
AMEMBASSY CARACAS PRIORITY
AMCONSUL HAMILTON PRIORITY

UNCLAS STATE 050860

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BD, CI, CS, DR, ES, GT,
HO, NU, PE, UY, VE

SUBJECT: FDA ADVISORY - FAULTY MANUFACTURING PRACTICES
AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-204-6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED:

(A) CARBOCAINE HCL 2 PERCENT (BRAND OF MEPIVACAINE HCL,
NF) WITH NEO-COBEFRIN 1:20,000 (BRAND OF LEVONORDEFRIN,
NF); COOK-WAITE LABORATORIES, INC., N.Y., N.Y. 10016
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(DISTRIBUTOR); INJECTABLES; 50/1.8 ML. CARTRIDGES PER

CAN OR 5/20 ML. VIALS PER BOX.

(B) CARBOCAINE 2 PERCENT (MEPIVACAINA, NF), NEO-NORDEFRINA 1:20,000 (LEVO-NORDEFRINA, NF); WINTHROP PRODUCTS, INC., NEUEVA YORK, NY 10016 E.U.A. (DISTRIBUTOR) INJECTABLE 50/1.8 ML. CARTRIDGES PER CAN.

LOT NUMBERS:

THESE PRODUCTS HAVE LOT NUMBERS CONSISTING OF THREE LETTERS FOLLOWED BY 2 DIGITS. ALL LOTS OF CARTRIDGES WITH AN "L" IN THE SECOND POSITION ARE BEING RECALLED.

ALSO, ALL LOTS WITH THE FOLLOWING COMBINATIONS IN THE FIRST TWO POSITIONS ARE BEING RECALLED: AN, CN, LN, PN, RN, UN. THE LOTS OF 20 ML. VIALS BEING RECALLED ARE OLB80 AND NLB80. -

DISTRIBUTION: 1/1/74 UNTIL 8/18/75

MANUFACTURER:

STERLING DRUG, INC.
33 RIVERSIDE AVENUE
RENSSELAER, NY 12144

RECALLING FIRM:

A.
COOK-WAITE LABORATORIES, INC.
90 PARK AVENUE
NY, NY 10016

B.
WINTHROP PRODUCTS
90 PARK AVENUE
NY, NY 10016

REASON FOR ADVISORY (RECALL)

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THROUGH VARIOUS INSPECTION REPORTS AND AT CONFERENCES HELD WITH THE CORPORATION'S RESPONSIBLE OFFICIALS, FDA ALLEGED THAT THE PRODUCTS WERE NOT AND HAD NOT BEEN MANUFACTURED IN CONFORMANCE WITH CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS AND THAT THERE WAS A QUESTION OF PRODUCT STERILITY. AFTER SEVERAL MORE MEETINGS AND IN-DEPTH REVIEWS OF BATCH RECORDS OF "STERILE" DRUG PRODUCTS, THE FIRM INSTITUTED A RECALL OF

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THE INJECTABLE PRODUCTS INVOLVED.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN INFORMED OF THE DETAILS OF THE RECALL AND IF THEY HAVE RECEIVED THE RCA GLOBAL CABLES SENT BY THE FIRM TO ALL FOREIGN DISTRIBUTORS ON AN INDIVIDUAL BASIS CONCERNING THIS RECALL. POSTS MAY ALSO WISH TO CONTACT HOST COUNTRY DRUG CONTROL AUTHORITIES INFORMING THEM OF THE RECALL SO THAT THEY MAY TAKE SUCH ACTIONS AS THEY DEEM APPROPRIATE.

3. FOREIGN CONSIGNEES AS FOLLOWS:

1. BERMUDA GENERAL AGENCY, HAMILTON BERMUDA
2. THE SYDNEY ROSS CO. Y CIA (LTDA), SANTIAGO, CHILE
3. STERLING PRODUCTS INTERNATIONAL S. A., SAN JOSE, COSTA RICA
4. STERLING PRODUCTS INTERNATIONAL, INC., SANTO DOMINGO, DOMINICAN REPUBLIC
5. CENTRAL AMERICA ADMINISTRATION, STERLING PRODUCTS INTERNATIONAL, INC. C.A.A. SAN SALVADOR, EL SALVADOR, C.A.
6. STERLING PRODUCTS INTERNATIONAL S.A., GUATEMALA CITY, GUATEMALA
7. STERLING PRODUCTS INTERNATIONAL S.A., TEGUCIGALPA, D.C., HONDURAS
8. LABORATORIOS FARMACEUTICOS DE NICARAGUA, S. A. MANAGUA, NICARAGUA
9. SYDNEY ROSS, S. A., LIMA, PERU
10. SYDNEY ROSS URUGUAY LIMITADA, MONTEVIDEO, URUGUAY
11. THE SYDNEY ROSS CO., CARACAS, VENEZUELA INGERSOLL

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: LABORATORY EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 02 MAR 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE050860
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.: AMS
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760080-0869
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Handling Restrictions: n/a
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TAGS: OGEN, ETRD, TBIO, BD, CI, CS, DR, ES, GT, FDA
To: SANTIAGO
MULTIPLE
Type: TE
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